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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,242	06/24/2003	Ye Fang	SP02-143	1181

22928 7590 09/20/2005

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,242	FANG ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,27 and 42-61* is/are pending in the application.

4a) Of the above claim(s) *3,6-8 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,9-18 and 42-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/08/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 42, 49, 50 is acknowledged and has been entered.

2. Applicant's cancellation of claims 19-26 and 28-41 is acknowledged and has been entered.

3. Applicant's addition of claims 51-61 is acknowledged and has been entered.

4. Claims 1-18, 27, 42-61 are currently pending.

5. Claims 3, 6-8, 27 have been withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 4-5, 9-16, 18, 42-50, 52, 54, 56-58, are rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al [US 6,699,719] in view of Ness et al [US 6,150,103].

With respect to claims 1, 42, 52, 54, 56-58, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines 65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence

microscope (column 32, lines 5-10). Yamazaki et al does not teach membranes deposited on an amine-presenting molecule or silane.

Ness et al, however, do teach a surface at least partially covered with a layer of an amine-presenting molecule such as polyethylenimine (PEI) for attaching biomolecules (column 2, lines 40-50). Ness et al further teach that PEI has been extensively used in the art for binding biomolecules, and is effective in this capacity due to its hydrophilicity, and the fact that PEI contains many amino groups which can form salts with acidic groups in a biomolecule (column 5, lines 18-32).

Therefore, it would have been obvious to one of ordinary skill in the art for the support to have a layer of PEI in the method of Yamazaki et al to bind biomolecules such as bilayer membranes, as Ness et al suggests that PEI is effective in binding biomolecules due to its hydrophilicity, and the fact that PEI contains many amino groups for forming salts with acidic groups in biomolecules.

8. With respect to claims 2, 4-5, Yamazaki et al teach that the arrayed membranes comprise gangliosides that bind to cholera toxin (column 31, example 8).

9. With respect to claim 9, the arrays are arranged into corrals of 500 microns^2 (column 31, lines 45-50).

10. With respect to claims 10-12, 14-15, 43, 44, Yamazaki et al teach that the toxin is labeled with Texas Red (column 64-66), the and the fluorescence microscope detects the corrals with bound cholera toxin as red(column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8).

11. With respect to claim 13, Yamazaki et al teach a competitive assay between a fluorescent antagonist (column 34, lines 65-67), and a receptor sensitive antagonist (column 35, lines 1-5).

12. With respect to claim 16, the substrate can be a silicon wafer (column 12, lines 20-26).

13. With respect to claim 18, the substrate can comprise well plate having surface detector array devices at the bottom of the wells (column 5, lines 18-20).

14. With respect to claim 45, the arrays are washed after incubation with the toxin (column 31, line 66 – column 32, line 4).

15. With respect to claim 46, the arrays are incubated with cholera toxin which binds to ganglioside GM1 (column 31, lines 62-65). The fluorescence microscope detects the corrals with bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8). Therefore, a decrease in the green fluorescence indicates binding of cholera toxin to ganglioside GM1.

16. With respect to claims 47-48, Yamazaki et al teach that measurement may be performed using capacitative detection or impedance analysis (column 18, lines 43-46).

17. With respect to claims 49-50, the sample is cholera toxin which binds to ganglioside GM1 (column 31, lines 62-65). The fluorescence microscope detects the corrals with bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8).

18. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al [US 6,699,719] in view of Ness et al [US 6,150,103], and further in view of Pluskal et al [US 5,004,543].

With respect to claim 17, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines 65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence microscope (column 32, lines 5-10). Yamazaki et al do not teach a microporous support.

Pluskal et al, however, teach a charge-modified, hydrophobic microporous membrane and further teaches that the membrane exhibits a combination of ionic and hydrophobic properties, rendering them highly effective for macromolecular adsorption applications under a variety of conditions (column 2, lines 35-46).

Therefore, it would have been obvious to one of ordinary skill in the art to have a charge-modified, hydrophobic microporous membrane as the support in the method of Yamazaki et al and Ness et al, as suggested by Pluskal et al, as the membrane is highly effective for macromolecular adsorption applications under a variety of conditions.

19. Claims 1, 2, 4-5, 9-16, 18, 42-51, 53, 55, 57-61, are rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al [US 6,699,719] in view of Nova et al [US 5,741,462].

With respect to claims 1, 42, 51, 53, 55, 57-61, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines 65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence microscope (column 32, lines 5-10). Yamazaki et al does not teach membranes deposited on an amine-presenting molecule or silane.

Nova et al, however, teach that γ-aminopropylsilanes and carboxysilanes are one of several molecules that can be used to treat a substrate in order to obtain an appropriate reactive moiety in order to link molecules or biological particles (column 15, lines 10-30).

Therefore, it would have an obvious to one of ordinary skill in the art for the array to been treated with γ-aminopropylsilane or carboxysilanes in the method of Yamazaki et al, as suggested by Nova et al, in order to obtain an appropriate reactive moiety in order to link molecules or biological particles.

20. With respect to claims 2, 4-5, Yamazaki et al teach that the arrayed membranes comprise gangliosides that bind to cholera toxin (column 31, example 8).

21. With respect to claim 9, the arrays are arranged into corrals of 500 microns^2 (column 31, lines 45-50).

22. With respect to claims 10-12, 14-15, 43, 44, Yamazaki et al teach that the toxin is labeled with Texas Red (column 64-66), the and the fluorescence microscope detects the corrals with bound cholera toxin as red(column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8).

23. With respect to claim 13, Yamazaki et al teach a competitive assay between a fluorescent antagonist (column 34, lines 65-67), and a receptor sensitive antagonist (column 35, lines 1-5).

24. With respect to claim 16, the substrate can be a silicon wafer (column 12, lines 20-26).

25. With respect to claim 18, the substrate can comprise well plate having surface detector array devices at the bottom of the wells (column 5, lines 18-20).

26. With respect to claim 45, the arrays are washed after incubation with the toxin (column 31, line 66 – column 32, line 4).

27. With respect to claim 46, the arrays are incubated with cholera toxin which binds to ganglioside GM1 (column 31, lines 62-65). The fluorescence microscope detects the corrals with bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8). Therefore, a decrease in the green fluorescence indicates binding of cholera toxin to ganglioside GM1.

28. With respect to claims 47-48, Yamazaki et al teach that measurement may be performed using capacitative detection or impedance analysis (column 18, lines 43-46).

29. With respect to claims 49-50, the sample is cholera toxin which binds to ganglioside GM1 (column 31, lines 62-65). The fluorescence microscope detects the corrals with bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8).

30. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al [US 6,699,719] in view of Nova et al [US 5,741,462], and further in view of Pluskal et al [US 5,004,543].

With respect to claim 17, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines 65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence microscope (column 32, lines 5-10). Yamazaki et al do not teach a microporous support.

Pluskal et al, however, teach a charge-modified, hydrophobic microporous membrane and further teaches that the membrane exhibits a combination of ionic and hydrophobic

properties, rendering them highly effective for macromolecular adsorption applications under a variety of conditions (column 2, lines 35-46).

Therefore, it would have been obvious to one of ordinary skill in the art to have a charge-modified, hydrophobic microporous membrane as the support in the method of Yamazaki et al and Nova et al, as suggested by Pluskal et al, as the membrane is highly effective for macromolecular adsorption applications under a variety of conditions.

Response to Arguments

31. Applicant's arguments with respect to claims 1, 2, 5, 9-18, 42-61 have been considered but are moot in view of the new ground(s) of rejection.

However, in response to applicant's argument with respect to Yamazaki et al and Ness that there is no motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is that PEI is very effective in the capacity of binding biomolecules due to its hydrophilicity, and the fact that PEI contains many amino groups which can form salts with acidic groups in a biomolecule (column 5, lines 18-32).

Conclusion

32. No claims are allowed.

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641

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09/18/05